

REMARKS

Claims 12 and 23 have been amended to expressly state the previously inherent requirement that the claimed methods be performed on humans in need of the claimed benefits. Support for these amendments exists throughout the present specification including the claims as originally filed.

Claims 12 and 23 have also been amended to delete 5-androstenediol sulfate from the claimed DHEA precursors. After further review, Applicants believe that 5-androstenediol sulfate is more appropriately identified as a DHEA metabolite than as a DHEA precursor. Claims 12 and 23 have been amended accordingly.

Claims 12, 13, 16-24, 27-33 and 36-45 are currently pending, although claims 36-45 have been withdrawn from consideration. Applicants note again their traversal of the restriction of claims 36-45 from prosecution. Applicants intend to seek rejoinder of these claims as appropriate upon indication of allowable subject matter.

Moreover, Applicants respectfully disagree with the Office Action's assertion (page 2) that "the difference in structures of the compounds herein does not make them distinct from each other. . ." Merely because the claimed compounds are searchable together does not mean that they are not distinct from each other. To the contrary, the claimed compounds are distinct from each other and, thus, each is separately patentable.

The Office Action rejected claims 12, 13, 16-18, 23, 24, 27 and 28 under 35 U.S.C. §102 as inherently anticipated by both Orentreich and Rosenbaum (U.S. patent 5,869,090). In view of the following comments, Applicants respectfully traverse these rejections and request reconsideration thereof.

It is undisputed that neither Orentreich nor Rosenbaum expressly discloses the claimed methods. The Office Action attempts to compensate for Orentreich's and Rosenbaum's complete failure to disclose the claimed methods by asserting that the cited

references inherently anticipate them. However, this assertion is factually and legally incorrect.

The assertion is factually incorrect because the claims require that the claimed methods be performed on human skin in need of the claimed benefits.¹ This “in need of” requirement is a limitation which must be disclosed in a reference before the reference can anticipate the claimed methods. *See, Jansen v. Rexall Sundown Inc.*, 68 U.S.P.Q.2d 1154 (in need of’ claims require the claimed method to be practiced with the intent to achieve the stated objective)(attached hereto at Tab A). However, neither Orentreich nor Rosenbaum discloses, either expressly or inherently, depigmenting, bleaching, improving the homogeneity of the color and/or pro-pigmenting human skin and/or superficial body growths in need of such benefits (that is, neither reference discloses applying the claimed DHEA compounds with the intent to achieve such benefits). Accordingly, neither Orentreich nor Rosenbaum anticipate the claimed methods.

Moreover, the assertion is legally incorrect. First, before the Patent Office can switch the burden of proof of showing non-inherency to Applicants, the Patent Office must provide some evidence or scientific reasoning to establish the reasonableness of the belief that the functional limitation is an inherent characteristic of the prior art. *See, Ex parte Skinner*, 2 USPQ2d 1788. In this case, the Patent Office has provided no such evidence. In this regard, Applicants’ specification cannot be used as evidence against them.

Second, for Orentreich or Rosenbaum to inherently anticipate the invention methods, these references must necessarily result in depigmenting, bleaching, improving the homogeneity of the color and/or pro-pigmenting human skin and/or superficial body growths

¹ For example, human skin “in need of” the claimed benefits would be the skin of a person who purchases a product containing one of the claimed DHEA compounds, where the product is marketed as being useful in

in need of such benefits. *See, Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955 (Fed. Cir. 2001)(inherent anticipation requires that the claimed invention necessarily result from the prior art disclosure); *Jansen v. Rexall Sundown Inc.*, 68 U.S.P.Q.2d 1154 (“in need thereof” language is not satisfied if the active ingredient is administered for a purpose other than the claimed purpose). In other words, the invention methods must naturally flow from Orentreich’s or Rosenbaum’s disclosure. *See, Eli Lilly, supra*. As noted in *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323 (CCPA 1981), the mere fact that a certain thing may result from a given set of circumstances is not sufficient to prove inherency: inherency may not be established by probabilities or possibilities.

Thus, something that is inherent must inevitably be the result each and every time. Here, neither Orentreich nor Rosenbaum inevitably leads to the claimed methods each and every time. Accordingly, neither reference can inherently anticipate the claimed methods.

Neither Orentreich patent cited on Applicants’ IDS (U.S. patents 4,496,556 and 4,542,129) discloses actual application of one of the claimed DHEA compounds to humans. Rather, Orentreich demonstrates applying DHEA to hamsters, not humans. Thus, Orentreich cannot inherently disclose achieving the claimed benefits on humans, so Orentreich cannot inherently anticipate the claimed methods.

Rosenbaum identifies numerous effects which DHEA application has on skin (fewer wrinkles, smoother skin and less roughness), yet he does not state that depigmentation or whitening occurred. Presumably, if Rosenbaum had achieved such depigmentation or whitening, Rosenbaum would have stated so since he identifies so many other effects. Because Rosenbaum is silent concerning the claimed benefits, it follows that such benefits

achieving at least one of the claimed benefits. Here, the customer’s intent would be to utilize the product to achieve the marketed benefit.

cannot occur on subjects in need of such benefits each and every time Rosenbaum is practiced. Thus, Rosenbaum cannot inherently anticipate the claimed invention.²

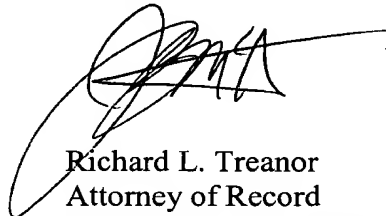
In view of the above, Applicants respectfully request that the inherent anticipation rejections under 35 U.S.C. § 102 are improper and should be withdrawn.

The Office Action also rejected claims 12, 13, 16-24 and 27-33 under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully submit that the above amendments to claims 12 and 23 have obviated this rejection, thereby rendering it moot. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Applicants believe that the present application is in condition for allowance. Prompt and favorable consideration is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Richard L. Treanor
Attorney of Record
Registration No. 36,379

Jeffrey B. McIntyre
Registration No. 36,867

Customer Number
22850

Tel #: (703) 413-3000
Fax #: (703) 413-2220

² Similarly, because Orentreich is silent concerning the claimed benefits, it follows that such benefits cannot occur on subjects in need of such benefits each and every time Orentreich is practiced. Thus, Orentreich cannot inherently anticipate the claimed invention as well.